State of California

Memorandum

To : SB 950 Registration Specialists

Date: December 8, 1994

Place: Sacramento

Phone: 324-3913

From : Department of Pesticide Regulation - Oleta Melnicoe
Pesticide Registration

Subject : Exemption and waiver Requests

Exemption and "waiver" requests are made by registrants who believe that one or more of the mandatory health effects studies should not be required for the active ingredient(s) in their product(s).

Exemption requests should be made by registrants pursuant to FAC Section 13127(e) (1) or (2). Please read this section of the law to familiarize yourselves with the basis for exemptions.

Section 13127(e) (1) relates to one or more products containing an active ingredient but not all the products containing that active ingredient. The mandatory health effects studies would still be required for the products that are not exempted. This type of product specific exemption does not have an expiration date.

Section 13127(e) (2) relates to all the pesticide products containing the active ingredient. If granted, the exemption expires at the end of three years at which time the mandatory health effects data are required.

The Department has the authority by law to grant an exemption from the data requirements; however, there is no authority for granting a "waiver". Decisions to not require or "waive" data are based on scientific recommendation by Department toxicologists.

A registrant may request that certain studies not be required (waived). The basis for these requests are varied. A few examples of "waiver" requests are as follows.

1. Data should not be required because insignificant exposure occurs from the use of the product and therefore the study is not required based on the interpretation of 40 CFR.

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2. Additional data should not be required for a given test because enough information is on file with the Department from studies determined to be unacceptable to assess the potential risk assessment.

3. Data should not be required because it is impossible to conduct the study.

Karen Flethcher works on exemption requests and requests to not require data based on interpretation of 40 CFR. These types of requests must be routed to Worker Health and Safety for evaluation.

Determinations to not require data based on the information available or on the feasibility of conducting a study are made by the Medical Toxicology Branch and are handled according to standard procedures if they are accompanied by data. If the request is not accompanied by data, then Fely Frank(1st 200) or Karen Fletcher (remaining active ingredients) would write a cover memo to route the request to the Medical Toxicology Branch.

Registrants often use the terms exemption and waiver interchangeably. They may also use the term waiver when referring to an objection to the data requirements pursuant to FAC 13131.2. It is therefore necessary to carefully read the cover letters submitted by the registrants to determine if the request is an exemption or a "waiver". Exemption requests should be directed to Karen. When you have identified the basis for a waiver request, you should **discuss the waiver with me.**

If you have further questions regarding exemptions and waivers, please see me.

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